

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 90-96, 98-126, 128-167, 173-174, 182 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Independent claim 90 does not recite adding a sample to the “overflow chamber” and as presently claimed no sample is added to the device. Also, it is not clear how the sample is “meter in the overflow chamber”. The Office has interpreted “metering” as implying a degree of controlling the sample flow. It is not clear what method steps are performed to accomplish the claimed “metering”. Similarly, the claim is not clear how the metered sample is added/ mixed with the reagent (e.g. has the sample been added from the “holding chamber” to the “analysis location”? ). Finally, the claim is not clear what steps are performed by the claimed “closable sample entry port.”

Claim 98 is not clear how the sample is forced into the overflow chamber by closure of the sample entry port. Presumably, closure of the port must cause a change in pressure or some other force must be exerted to force the sample. It is not clear how simply closing a port can exert a force on a fluid. For the purposes of examination, it will be assumed the pump changes the pressure in the system to force the sample into the overflow chamber.

Claim 101 is not clear what method steps are performed by the “pre-sensor chamber.”

Claim 115 is not clear how the overflow chamber is treated to impart a high energy surface to the interior. For the purposes of examination, it will be assumed pressure is intended.

Claim 120 is not clear what method steps are intended by “ ... a lower interior surface-to-volume ration ...” because these appear to be structural limitations. Furthermore, even if these limitations were considered as a structural limitations, it is not clear what structure is intended by “ ... a lower...”.

Claim 125 is not clear what products are intended. If these are well known in the art, please reference the appropriate portions of the specification or supply corroborating evidence in your response.

Claim 182 is not clear what structure is intended by a “pre-sensor.”

***Claim Rejections - 35 USC § 102***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1.

Claims 90-96, 98-126,128- 136,144-146,148, 150-158, 167, 173-203 and 212-215 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Sheppard et al. (USP 6,143,247).

Sheppard et al. a method and apparatus for the detection of an analyte in a sample. Column 3 lines 18-25 teach a detection chamber where a specific binding reagent is supplied that binds to the analyte of interest. This chamber has been read on

the claimed "analysis location." Column 3 lines 65-67 teaches various detector that have been read on the claimed "sensor." Column 4 lines 23-30 teach the structure also includes "... input means, fluid waste receptacles, overflow reservoirs, wash buffer reservoirs, fluid waste receptacles or reservoirs containing ..." that have been read on the claimed "holding chamber" and "overflow chamber." Column 6 lines 1-12 teach a metered amount of sample is transferred to a detection cell and any excess fluid from the metered amount is placed into an overflow chamber. The metered amount is between 10 microliter and 150 microliters. This has been read on the claimed "metering a portion of the sample by retaining the excess in the overflow chamber" and the claimed volume ranges. Column 13 lines 34-45 teach the sample can be moved by mechanical means such as pumping of air which has been read on the claimed "pump". The claimed "capillary stops" have been read on the taught pump that controls the flow of the fluids through the device (e.g. stops and starts the flow). Column 16 lines 9-15 teach treating the surface with a gas plasma which has been read on the claimed "corona treated" surface. Column 17 lines 26-36 teach treatment of the surface with hydrophobic materials and has been read on the claimed "hydrophobic areas." Sheppard et al. teach dyes and buffers such as HEPES that have been read on the claimed reagents. With respect to the limitations of claim 120, the Office notes that chamber(27) is larger than chamber(29) and has been read on the "overflow chamber" and "holding chamber" respectively.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 137-143,143,149,159-166,204-211 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sheppard et al. in view of Zelin et al. (USP 5,124,661).

See Sheppard et al. *supra*.

Sheppard et al. are silent to the claimed conductimetric and amperometric sensors.

Zelin et al. in their abstract a reusable blood testing cartridge that comprises a combination of amperometric and conductometric sensors for the analysis of blood. Column 4 lines 8-19 teach these sensors are advantageous because they do not need to be replenished with chemicals.

It would have been within the skill of the art to modify Sheppard et al. in view of Zelin et al. and use a combination of amperometric and conductometric sensors to gain the above advantages.

### ***Response to Arguments***

Applicant's arguments filed 7/8/09 have been fully considered but they are not persuasive.

Applicants' state the amendments to claim 90 have clarified where the metered sample is created. The Office agrees, this issue has been addressed, but maintains the new issues of where the sample is added is now raised in the above 35 USC 112 second paragraph rejections with respect to claim 90.

Applicants, traverse the 35 USC 112 second paragraph rejections over claims 98 stating the conclusions reached by the Office are not correct and pages 17-18 of the specification teach the forces to move the fluid. While the specification teaches how the fluid is moved, the Office maintains the claims do not with sufficient clarity to meet the standards of 35 USC 112 second paragraph. Clarification could be achieved by either importing the appropriate limitations from the specification or invoking 35 USC 112 6th paragraph and the appropriate "means for" language.

Applicants, traverse the 35 USC 112 second paragraph rejections over claims 101 and 182 stating the location of the "pre-sensor chamber" is clearly taught in figure 4 and on page 17. Again, the Office agrees the specification teaches the location of the "pre-sensor chamber", but the claims do not teach the location of the "pre-sensor chamber" with sufficient clarity to meet the standards of 35 USC 112 second paragraph. Clarification could be achieved by either importing the appropriate limitations from the specification or invoking 35 USC 112 6th paragraph and the appropriate "means for" language.

Applicants, traverse the 35 USC 112 second paragraph rejections over claim 115 stating page 15 of the specification teaches how the surface is treated. The Office maintains the claim does not with sufficient clarity to meet the standards of 35 USC 112 second paragraph. Clarification could be achieved by either importing the appropriate limitations from the specification or invoking 35 USC 112 6th paragraph and the appropriate "means for" language.

Applicants' amendments have clarified the 35 USC 112 second paragraph issues concerning the term "lower". However, the Office maintains it is not clear how the limitations directed to the volume of the chambers further limits the pending method claims.

Applicants' traverse the 35 USC 112 second paragraph rejections over claim 126 stating page 13 of the specification teaches what products are formed. The Office maintains the claim does not with sufficient clarity to meet the standards of 35 USC 112 second paragraph. Clarification could be achieved by either importing the appropriate limitations from the specification or invoking 35 USC 112 6th paragraph and the appropriate "means for" language.

Applicants' traverse the 35 USC 102(e) rejections over Sheppard et al. on the basis this reference fails to teach the claimed pumping a metered sample through the overflow chamber. The Office maintains Sheppard et al. teach pumping a sample through a chamber to receive the metered portion that used for subsequent analysis. Applicants' state Sheppard et al. are silent to the claimed "pump". The Office maintains Sheppard et al. clearly teach in column 13 lines 34-41 use of a pump to move to the sample and is indistinguishable from the instant claims.

Applicants' argue the overflow chamber(23) taught by Sheppard et al. is entirely separate from the taught analysis chamber(24) and does not meet the instant limitations that the two are connected. The Office maintains the instant claim language is sufficiently broad to have been read on the taught series of connected chambers, such

as the taught sample entry port(21) which supplies the sample to sequential chambers(27-29) and eventually to analysis chamber(24).

Applicants' traverse the 35 USC 103 rejections because the 35 USC 102(e) rejections above are untenable. The Office maintains all of the rejections of record are proper.

1. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

1.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lyle A. Alexander whose telephone number is 571-272-1254. The examiner can normally be reached on Monday, Tuesday and Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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